REMARKS

Claims 110-115 and 117-122 are pending.

Applicant thanks the Examiner for the interview of May 20, 2004, as well as for indicating that the Affidavit of Dr. Cohen, establishing a date of conception of the subject matter of the present invention prior to June 12, 1996, is effective to remove Mogul et al. (J. Clinical Endocrincology, Vol. 8, No. 12, 1996, pp. 4492-4495) as a reference against this application. Applicants additionally thank the Examiner for withdrawing the rejection of claims 110-115, 117 and 118 under 35 USC § 103(a) as being unpatentable over Reaven (Diabetes, Vol. 37, pp. 1595-1601, Dec. 1988) in view of Caretta et al. (J. Hypertension, Vol. 7, Supp. 6, pp. s196-s197, 1989) and Verber et al. (Life Sciences, Vol. 34, pg. 1371-1378, 1984).

Claims 110-115, 117 and 118 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over Reaven, in view of Orskov et al. (Metabolism, Vol. 45, No. 2, pp. 211-217, 1996) and Veber et al.

The Office Action asserts that Reaven presents that there may be a link between insulin resistance and hypertension (or high blood pressure), i.e., one of the listed risk factors for syndrome X. Thus, because Orskov et al. teaches that octreotide, i.e., a somatostatin analog, is effective to treat insulin-dependent diabetes (IDDM) patients, to control a reduction in insulin resistance in IDDM patients, the Office Action assumes it would have been obvious to treat hypertension by administering octreotide.

The present claims recite treating a "a patient exhibiting syndrome X," rather than "a patient exhibiting symptoms of syndrome X." However, based upon the description of syndrome X in the present specification, the Office Action maintains that syndrome X is similar to, if not identical to, insulin resistance. In contrast, the last sentence of the first paragraph on page 1596 of Reaven states, "insulin resistance, by itself, is not sufficient to produce the full blown syndrome [X]." Thus, the cited references themselves distinguish syndrome X from simple insulin resistance.

In any event, Applicant respectfully presents the analysis of the Office Action is flawed. The study relied upon on in Reaven was performed on normal rats, which shows only a

"correlation" between insulin resistance and hypertension. However, Reaven states "great care should be exercised in the extrapolation of results of studies in normal rats to humans with hypertension." Thus, Reaven suggests that the data obtained from normal rats may not be applicable to humans with hypertension.

Additionally, although this reference suggests that there may be "correlation," the paragraph bridging pages 1602 and 1603 merely indicates the possibility of a causal relationship and serves as an invitation to perform additional experiments. Thus, this reference fails to sufficiently provide any causal relationship between insulin-resistance and hypertension. Accordingly, as none of the references identify such a causation, no prima facie obviousness has been established.

Moreover, the reliance on the combination of Reaven and Orskov et a l. also fails to support the alleged prima facie obviousness. The study of Orskov et al. is based on Insulin Dependent Diabetes Mellitus (IDDM). As is generally known, in IDDM patients, there is a lack of insulin, and a high sensitivity to insulin, i.e., no insulin resistance. Therefore, Applicant respectfully presents that a study based in IDDM patents is not a good model to study the ability of a drug to increase the sensitivity to insulin, as in IDDM patients, the sensitivity to insulin is already high . Thus, the teaching of Orskov et al. in no way supports the Examiner's allegations that the combination with Reaven would establish a prima facie cased of obviousness.

New claim 120 depends from claim 110 and recites "wherein the pharmaceutically effective dosage is at least 40 μg/kg/day." In contrast, Orskov et al. teaches to use a significantly lower dosage of octrotide, i.e., 1 μg/kg/day. See Orskov et al., pg. 211, second column and Fig. 1. Applicant respectfully presents that there is neither a teaching nor suggestion to multiply this dosage by 4000%.

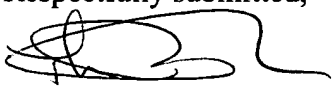
New claim 119 is supported at pages 1-2 of the present application and recites a method for simultaneously treating a combination of insulin resistance and another condition in a human patient, wherein the other condition is high blood pressure, dislipidemia, elevated triglyceride levels, low HDL, high LDL, blood coagulation due to elevated PGA-1 levels, or obesity. As none of the cited art, alone or in combination, teach nor suggest to administer one of the recited

compositions to a human patient exhibiting insulin resistance and of the recited conditions, Applicant respectfully presents that claim 119 is allowable.

Finally, Applicant reiterates the election of Cyclo[N-Met-Ala-Tyr-D-Lys-Val-Phe], and notes that claims 117 and 118 have been withdrawn as being directed to non-elected subject matter. However, upon the allowance of one generic claim, e.g., independent claim 110, Applicant respectfully requests consideration of a reasonable number of additional species under 37 CFR § 1.141(a).

In view of the above, it is respectfully submitted that all objections and/or rejections are overcome. Thus, entry of the above amendment and passage of this application to allowance, is respectfully requested.

Respectfully submitted,



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Thomas P. Pavelko
Registration No. 31,689

STEVENS, DAVIS, MILLER & MOSHER, L.L.P.
1615 L Street, N.W., Suite 850
Washington, D.C. 20036
Telephone: (202) 785-0100
Facsimile: (202) 408-5200 or (202) 408-5088

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